

### **REMARKS**

Claims 1-10 are pending in the present application. Claims 1, 3 and 8-10 are herein amended. New claims 11-14 are herein added. No new matter has been presented.

Claim 1 is herein amended to specify a fluorine-containing nonaromatic polyisocyanate component (A). Claim 3 has been amended to correct a typographical error. Claim 8 has been amended into a method for bonding body tissues. Supports for the amendments can be found in paragraphs [0012], [0013], [0050], [0069], [0123] and [0153] of U.S. publication of the present application.

### **Claim Rejections - 35 U.S.C. §112, second paragraph**

Claim 8 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner asserts that it is unclear what limitations are conveyed by the phrase, “medically suitable”.

Applicants herein amend claim 8 to remove the phrase “medically suitable”, thus mooting the rejection.

### **Obviousness-Type Double Patenting**

Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 7, 8, 10-16, and 18-20 of copending

Application No. 10/499,331 in view of Hiraishi et al. ('266) or Nakamura et al. (US 2003/0225239) or Sparer et al. (US 2004/0033251) or Felt et al. (US 2005/0060022).

Applicants note that Application No. 10/499,331 became abandoned after October 14, 2008. This was confirmed in a Notice of Abandonment received from the Patent Office dated October 31, 2008. Therefore, the rejection should be withdrawn.

**Claim Rejections - 35 U.S.C. §103(a)**

Claims 1-10 are rejected under 35 U.S.C. §103(a) as being unpatentable over WO 03/051952 in view of Hiraishi et al. ('266) or Nakamura et al. (US 2003/0225239) or Sparer et al. (US 2004/0033251) or Felt et al. (US 2005/0060022).

The Examiner asserts that the use of phenolic antioxidants that correspond to Applicants' claimed phenolic radical scavenger within polyurethanes, suitable for use within medical applications, was known at the time of invention.

Applicants have argued unexpected results that rebut the *prima facie* case of obviousness. The Examiner has considered Applicants' examples within the specification and the examples within Applicants' 37 C.F.R. §1.132 declaration filed December 26, 2007; however, the Examiner asserts that the showings are insufficient to rebut the *prima facie* of obviousness because the examples are not commensurate in scope with the claims.

The Examiner asserts that Applicants' examples are limited to specific polyisocyanates, specific polyol compounds having specific characteristics, and specific phenolic radical scavengers used in specific amounts, but Applicants' claimed are not so limited. The Examiner

concludes that because the scope of the claims is broader than the scope of the examples and showings, Applicants have failed to provide adequate showings of unexpected results for the full scope of the claims.

According to the Manual of Patent Examining Procedure (MPEP) §2145, when considering whether proffered evidence is commensurate in scope with the claimed invention, Patent Office personnel should not require the applicant to show unexpected results over the entire range of properties possessed by a chemical compound or composition. See, e.g., *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987).

Evidence that the compound or composition possesses superior and unexpected properties in one of a spectrum of common properties can be sufficient to rebut a *prima facie* case of obviousness. For example, a showing of unexpected results for a single member of a claimed subgenus, or a narrow portion of a claimed range would be sufficient to rebut a *prima facie* case of obviousness if a skilled artisan “could ascertain a trend in the exemplified data that would allow him to reasonably extend the probative value thereof.” *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980).

Applicants note that the present specification uses five exemplary examples, and compares them with six comparative examples. The Declaration under 37 C.F.R. §1.132 dated December 12, 2007 and filed on December 26, 2007 included an additional five comparative examples, bringing the number of comparative examples to 11. Applicants refer herein to the above data, and provided additional data in the form of a subsequent Declaration under 37 C.F.R. §1.132.

With respect to the claimed fluorine-containing aliphatic diisocyanate, Applicants note that in the present invention, experimental data is shown of the medical adhesive using a diisocyanate represented by  $\text{OCN-CH}_2\text{-Rf-CH}_2\text{-NCO}$  (hereinafter referred as “a”), but not shown using a diisocyanate represented by  $\text{OCN-Rf-NCO}$  (hereinafter referred as “b”) as “a fluorine-containing aliphatic diisocyanate (A11) having 5 to 22 carbon atoms”.

However, Applicants submit that the claimed invention is disclosed and results supported as discussed below even if not showing examples and data directed to b.

As can be expected from Examples of the medical adhesives using diisocyanates with or without fluorine (for example, Comparative Example 1 and Comparative Examples 5 to 11), inclusion of fluorine into the isocyanate tends to lead to improvement in wet adhesive strength (2H).

Applicants submit that a main factor contributing to the wet adhesive strength (2H) is an amount of fluorine in the isocyanate. There is really not much difference in the amount of the isocyanate between a and b (the former: about 35 to about 68%; the latter: about 44 to about 71%). Therefore, one skilled in the art would have readily expected that the medical adhesive using b is equivalent in wet adhesive strength (2H) as the medical adhesive using a.

The fact that a cured film of the medical adhesive using a fluorine-containing isocyanate turns into liquid is attributed to oxidative decomposition of the cured film. The amount of fluorine in the isocyanate is also believed to relate to the oxidative decomposition. Due to the same reason as above, it is supposed that there is really not much difference in a degree of deterioration of the cured film between the medical adhesives using a or b. Accordingly, a

phenolic radical scavenger sufficiently has an oxidative decomposition prevention effect to the medical adhesive using b, and it is turned out that a wet adhesive strength (5D) is substantially equivalent as a wet adhesive strength (2H).

As discussed above, the claimed invention is disclosed even though an example using b is not shown.

With respect to the hydrophilic polyol, Applicants note that in the present specification and supporting data, there is shown experimental data of the medical adhesive using a polyether polyol (B1-1), but not shown about a polyester polyol (B1-2) as “a hydrophilic polyol (B1)”.

However, the Applicant believes that the claimed invention is disclosed as discussed below even though not showing (B1-2).

Regarding urethane resins using an isocyanate without fluorine (e.g. TDI and MDI), Applicants submit that there is not much difference in degree of oxidative decomposition regardless of whether a polyether polyol or a polyester polyol is used. For this reason even in the medical adhesive using a fluorine-containing isocyanate, the respective sites derived from a polyether polyol and a polyester polyol presumably have a comparable degree of oxidative decomposition. It is believed that an addition effect of the phenolic radical scavenger is comparable in both cases. Further, it has been turned out empirically that an adhesive strength depends on a hydrophilicity of a polyol entity.

Considering the facts in toto, Applicants submit that it is not necessary to show an example using a polyester polyol in order to claim the invention. Applicants submit that the claimed invention is disclosed by and understood from the present examples.

With respect to phenolic radical scavenger (PRS), Applicants note that in Examples of the description, only examples using a polymeric phenolic radical scavenger are disclosed. Applicants submit herewith a Declaration providing data on a monophenolic radical scavenger and a bisphenolic radical scavenger.

From the data shown in the Declaration, the monophenolic radical scavenger and the bisphenolic radical scavenger are expected and understood to have equivalent effect to the polymeric phenolic radical scavenger.

Consequently, Applicants submit that the claimed invention is disclosed also from the viewpoint of the phenolic radical scavenger.

As discussed above in detail, the subject matter that the Applicant claims as the invention is disclosed sufficiently and supported by data commensurate in scope with the claims. Therefore, unexpected results of the preset invention should be acknowledged over the cited documents. Accordingly, it would not have been obvious for one skilled person in the art to have arrived at the subject matter of the claims at the time of the invention.

In view of the aforementioned amendments and accompanying remarks, Applicants submit that the claims, as herein amended, are in condition for allowance. Applicants request such action at an early date.

If the Examiner believes that this application is not now in condition for allowance, the Examiner is requested to contact Applicants' undersigned attorney to arrange for an interview to expedite the disposition of this case.

Application No. 10/594,627  
Attorney Docket No. 063012

Amendment under 37 C.F.R. §1.114  
Amendment filed February 26, 2009

If this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,

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Enclosure: Declaration under 37 C.F.R. §1.132 dated December 12, 2007